

## REMARKS

Claims 1 and 4 are currently pending in the application. Claim has been amended to include “before the occurrence of an ischemic event.” Support for the amendment is found the application on p. 5, lines 21-24 and p. 10, lines 29-30, and the Examples, among other places.

Claim 1 (and thus claim 4) stands rejected on the non-statutory basis of obviousness-type double patenting relative to claims 1-19 of US Patent No. 6,326,365 B1 (see Office Action, p. 2) and claims 1- 8 of US Patent No. 6,399,078 B1 [sic], presumably intended to be US 6,339,078 B1 (see Office Action p. 3). Applicants respectfully submit that the Examiner has impermissibly applied the non-statutory double-patenting doctrine with respect to the ‘365 and the ‘078 patents because the cited patents and the pending application are not commonly owned. According to MPEP § 804 Part II, B. 1, “In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? ... Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed *in a commonly owned patent...*”), emphasis added. In this case, the Examiner has incorrectly concluded that the ‘365, ‘078 patents and the pending application are commonly owned. They are not. The ‘365 and ‘078 patents are owned by The University of Florida Research Foundation, Inc. and MitoKor, Inc., jointly. The pending application is owned solely by The University of Florida Research Foundation, Inc.

Because of the misapplication of the obviousness-type double patenting rejection, Applicants respectfully submit that claim 1 is not an obvious variant of claims 1-19 of the ‘365 patent or claims 1-8 of the ‘078 patent. Applicants therefore respectfully request withdrawal of the double patenting rejections.

The Examiner has also rejected claim 4 under 35 U.S.C. § 112, para. 1, alleging lack of written description for the language “said time-course duration extends over a plurality of months”, asserting that the application does not describe what time-course duration or time-period wherein the administration of 17- $\alpha$  estradiol is effective over a plurality of months” (see Office Action, p. 4). Claim 4 is amended to recite that the time course duration “may extend from days to months depending on the particular susceptibility profile of the subject.” Support for this amendment is found in the application on p. 10, last paragraph. As amended, Applicants

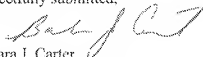
respectfully submit that claim 4 is sufficiently described in the written application and meets the requirements of 35 U.S.C. § 112, para. 1. Applicants therefore request withdrawal of the rejection based on lack of written description.

In conclusion, in view of the above arguments and the amendment to claim 4, Applicants respectfully submit that the application is in condition for allowance and request reconsideration of same.

Applicants believe that a three-month extension of time is required along with the associated extension fees. In the event that additional fees are due, Applicants authorize the Commissioner to charge deposit account number 19-4972 for any additional fees that may be required for the timely consideration of this application.

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Respectfully submitted,



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